REMARKS

Reconsideration of the present application in light of the amendments and remarks set forth here is respectfully requested.

Claims 1, 2, 5, 7, and 8 were pending in the subject application. Claim 8 was previously withdrawn. Claim 1 has been amended herein to clarify certain aspects of Applicant's claimed invention. Claim 2 has been cancelled herein in view of the amendment to claim 1. Claim 5 has been amended to depend from claim 1. Support for the amendment to the claim may be found throughout the instant application as filed, for example, at pages 16-20. The amendment to claim 1 and cancellation of claim 2 are not to be construed as acquiescing to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by the amendment in a related divisional, continuation or continuation-in-part application. Claims 1, 5 and 7 are now under consideration.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1, 2, 5, and 7 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. As noted above, claim 2 has been cancelled without prejudice. Accordingly, the current rejection under 35 U.S.C. § 112 applies only to currently pending claims 1, 5 and 7. The Action asserts, in particular, that claim 1 "requires that the bacteria and nutrient within the composition be 'mixed and incubated prior to administration to the subject," and that this is "confusing." More specifically, the Action asserts that "it is not clear whether the claims are drawn to a kit in which components (i)-(iv) are mixed together or whether the components are provided separately." The action further asserts that "the limitation 'prior to use' is confusing." Without acquiescing to the rejection and solely to advance prosecution, claim 1 has been amended to more clearly identify physical characteristics of the kit to which claim 1, and thus claims 5 and 7, are directed. In particular, the kit to which claim 1, as amended, is directed comprises a mixture of bacteria, a nutrient, and ascorbic acid, and separately further comprises an antimicrobial agent. As claimed, the kit is formulated for ingestion by oral administration, that is, non-topically, to the gut. The term "gut" is well known in the art to commonly refer particularly to the stomach and intestine. Formulations suitable for

administration orally to the gut are disclosed, for example, at pages 16-20 of the instant application as filed. It is further readily apparent from the disclosure that the kit, as claimed, provides probiotic bacteria and additional materials to stimulate growth of the bacteria in the gut.

Applicant thus submits that the rejection of claim 1, and thus claims 5 and 7, under 35 U.S.C. § 112, second paragraph, has been overcome. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this ground for rejection.

Rejection Under 35 U.S.C. § 103(a)

Claims 1, 2, 5, and 7 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Farmer (U.S. Patent No 6,645,506), in view of Jaffe (U.S. Patent No. 3,853,454). As noted above, claim 2 has been cancelled without prejudice. Accordingly, the current rejection under 35 U.S.C. § 103(a) applies only to currently pending claims 1, 2 and 7. Applicant traverses this ground for rejection.

Applicant respectfully submits that the Action has failed to establish a *prima facie* case for obviousness of the claimed subject matter, as amended herein, over Farmer ('506), in view of Jaffe ('454). In this regard, Applicant submits that the Office has improperly combined elements allegedly disclosed by Farmer, in view of Jaffe, in attempting to make a *prima facie* case for obviousness. In particular, Applicant submits that the Office has selectively cited the disclosure of alleged elements without consideration of the context within which such alleged elements are found, that is, disregarding the prior art reference(s) as a whole. The Action asserts as follows:

> Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide (column 25, line 57, through column 26, line 25; "Formulation 1"). Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27). Farmer teaches that the composition may further comprise an antimicrobial agent, for example an anti-fungal compound such as nystatin (column 22, lines 28-51, especially line 45) and an antioxidant (column 17, lines 33-35). Farmer teaches a formulation comprising *Bacillus coagulans* and fructooligosaccharides (column 25, line 62, through column 26, line 4) and mixing said formulation into water (column 20, lines 42-53). Farmer teaches that the formulation may be modified for administration via various means, including oral administration (column 19, lines 36-47).

The Action further asserts as follows:

> A person of ordinary skill in the art would have had a reasonable expectation of success in including ascorbic acid in the composition of Farmer because Farmer suggests adding 'known antioxidants,' and Jaffe teaches that ascorbic acid was a know antioxidant at the time of the invention of Farmer. The skilled artisan would have been motivated to add ascorbic acid to the composition of Farmer because Farmer suggests including antioxidants to facilitate the growth and germination of the bacteria within the composition (column 17, lines 21-42).
>
> A person of ordinary skill in the art would have had a reasonable expectation of success in including nystatin in the composition of Farmer because Farmer specifically contemplates such an addition; at column 21, lines 55-62, Farmer suggests a composition comprising probiotic bacteria and an anti-fungal compound. The skilled artisan would have been motivated to include nystatin in the composition of Farmer for the expected benefit that fungal infections might be prevented by the administration of said compound.

The Action thus asserts that a *prima facie* case for obviousness has been established as follows:

> It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute one or more of the bacteria at columns 21-22 into the exemplified composition of Farmer because Farmer teaches that the bacterial are art-accepted substitutes for each other. It would have been further obvious for the artisan to add nystatin to the composition of Farmer because Farmer teaches that the inclusion of antifungals in bacterial compositions retards the growth of yeast and molds (column 5, line 62, through column 6, line 12). It would have been further obvious for the artisan to add ascorbic acid to the composition of Farmer because Farmer teaches that the inclusion of antioxidants in bacterial compositions facilitate the growth and germination of the bacterial therein (column 17, lines 21-42).

Applicant respectfully disagrees with these grounds for rejection of the instantly claimed subject matter, as amended herein.

Applicant submits that the cited references, either alone or in combination, fail to teach, disclose, or suggest the subject matter as currently claimed and under consideration in the present application. As noted above, Applicant submits that in the Action elements allegedly disclosed in the references are combined without adequate consideration of the cited reference(s) as a whole.

In order to more clearly discuss and contrast the currently pending claims, as amended herein, and the teachings of Farmer, in view of Jaffe, particularly as asserted in the Action, it may be helpful to first review pertinent aspects of the disclosure by Farmer, including, in particular, aspects of the disclosure cited in the Action. The Abstract of Farmer states that the "invention discloses compositions ... suitable for topical application ... for inhibiting the growth of bacterium, yeast, fungi, virus, and combinations thereof." The Abstract further summarizes that the compositions may be derived from bacterial species, spores, or extracellular products. Farmer further discloses in Figures 2-4 a variety of disease indications, and the corresponding infecting microbes, for which the compositions taught by Farmer for topical applications may be used, in particular, treatment of bacterial (Figure 2), fungal (Figure 3), and yeast (Figure 4) infections of skin or certain mucous membranes. Farmer includes, particularly at columns 23-41, a number of exemplary embodiments, all of which relate to compositions for topical applications to treat infections of skin or mucosa. Farmer discloses a variety of formulations suitable for topical administration, including, for example, washes to treat infections of oral or vaginal linings. The instant application is directed to a kit comprising two elements: (1) a mixture of one or more beneficial bacteria, a bacterial nutrient, and ascorbic acid, and (2) separately an anti-fungal agent, in particular, for example, nystatin. The kit elements, as claimed, are formulated for ingestion by oral administration to the gut. Applicant submits that Farmer, in view of Jaffe, fails to teach, disclose, or even suggest all of the elements of the claimed subject matter, as amended. In particular, the cited references fail to teach or suggest a kit, as claimed herein. In fact, the references, taken individually or together, fail to teach or suggest any compositions formulated for oral administration to the gut.

Further, regarding certain aspects of the rejection, Applicant respectfully submits, as noted above, that the Action has improperly combined certain elements allegedly disclosed in Farmer. Applicant submits that all compositions, and any components thereof, disclosed throughout Farmer are described as being formulated or suitable for topical application to inhibit growth of microorganisms. None are disclosed or suggested as being formulated or suitable for ingestion. For example, referring to the grounds for rejection as summarized above, the "Formulation 1" at columns 25-26, as cited in the Action, describes a "bathing formulation" or a

wash. In this regard, "mixing [a] formulation into water (column 20, lines 42-35)," as also cited in the Action, describes a "therapeutic bath" formulated for "contacting the infected tissue ... as by 'taking a bath' in the conventional sense." Further in this regard, at column 19, lines 36-47, Farmer discloses a therapeutic composition "formulated to be suitable for application ... as a wash for the mouth (e.g., for oral thrush) ...." The latter is alleged in the Action to provide support for oral administration of the composition. However, it clearly only teaches oral administration of a wash, such as for treatment of the lining of the mouth, as in oral thrush; it does not teach or suggest a formulation suitable for ingestion orally into the gut. Concerning the assertion in the Action that "Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27)," Applicant notes that this section relates to compositions comprising bacterial supernatants derived from various bacteria, as listed, not to the bacteria. This section further relates to compositions also comprising a "carrying agent," such as Emu oil, to "facilitate penetration of these therapeutic compositions through the various dermal and cuticular membranes and tissues" for the treatment of dermal diseases (column 21, lines 24-61). This section does not teach compositions of bacteria, nor does it even teach or suggest compositions of the bacterial supernatants for oral ingestion into the gut. The Action asserts that "the composition may further comprise an antimicrobial agent ... such as nystatin (column 22, lines 28-51, especially line 45)...." As in the case of the mixtures of probiotic bacteria discussed immediately above, the section asserted in the Action as teaching anti-microbial agents, including nystatin relates specifically to compositions comprising bacterial supernatants, not bacteria. Further, as above, this section does not teach compositions of bacteria, nor does it teach or suggest compositions of bacterial supernatants for oral ingestion into the gut. Concerning the discussion in the Action related to including ascorbic acid in the composition of Farmer, Applicant submits that neither Farmer nor Jaffe, taken alone or together, teaches or suggests incorporation of ascorbic acid into a kit, or even a composition, formulated or suitable for ingestion orally into the gut. Nevertheless, Applicant has the following further comments related to the further assertions in the Action. The Action, at page 7, expresses confusion related to Applicant's prior submission concerning this aspect. Similar to the position taken in the previous Action, it is asserted in the

current Action that "Farmer specifically teaches a motivation for including antioxidants in the composition, *i.e.*, facilitating the growth and germination of the bacteria within the composition…." Column 17, lines 21-42, of Farmer is provided as support for this assertion. This paragraph from Farmer reads as follows: "The formulation for a therapeutic composition of this invention may include other probiotic agents or nutrients for promoting spore germination and/or Bacillus growth. The compositions may also include known anti-microbial, anti-viral, anti-fungal, or anti-yeast agents … The therapeutic compositions may also include, but are not limited to the inclusion of: known antioxidants … buffering agents … lubricants … sunscreens … and other cosmetic agents … Thickening agents may also be added …." (underlining added) Applicant notes that in quoting from this paragraph, the underlined portions were not included and thus submits that the paragraph was selectively, and inappropriately, edited to support the assertion. Applicants submit that this paragraph, when considered as a whole, simply lists a variety of other agents that may be included in topical therapeutic compositions and fails to provide support, as asserted in the Action, for use of "known antioxidants," any more than for use of "sunscreens" or "other cosmetic agents," as probiotic agents or nutrients. Finally, the Action asserts at page 9 that "Farmer explicitly teaches that his composition is suitable for oral administration." As noted above, this assertion is based on disclosure by Farmer of formulation of a therapeutic composition as a mouth wash (column, 19, lines 38-39). Farmer does not teach or suggest any composition formulated or suitable for ingestion orally into the gut.

Accordingly, Applicant submits that Farmer, either alone or in view of Jaffe, discloses compositions formulated and suitable broadly and specifically only for topical administration. Applicants further submit that compositions taught by Farmer are therapeutic compositions designed to inhibit microbial growth. Applicant submits that Farmer and/or Jaffe fail to teach, disclose, or even suggest any composition or kit, or any components thereof, formulated for ingestion orally into the gut for any purpose. In particular, Farmer and/or Jaffe fail to teach or even suggest a composition or kit, which is formulated for oral ingestion to induce the population or re-population of the gut with beneficial bacteria.

In view of the above amendments and remarks, Applicant submits that these grounds for rejection of claims 1, 5 and 7 under 35 U.S.C. § 103(a) have been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1, 2, 5 and 7 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Wynne et al. (WO 03/033681; reference N) taken in view of Muramatsu et al. (US 5,334,516) and Costanzo et al. (US 5,518,740). As noted above, claim 2 has been cancelled without prejudice. Accordingly, the current rejection under 35 U.S.C. § 103(a) applies only to currently pending claims 1, 2 and 7. Although Applicant disagrees with these grounds for rejection, Applicant respectfully submits that the Wynne et al. reference is not prior art under 35 U.S.C. § 102(e) and cannot be used as the basis for a rejection under 35 U.S.C. § 103(a). As described in the accompanying declaration under 37 C.F.R. § 1.131 executed by the inventor ("the Declaration"), the inventor conceived of and diligently reduced to practice the present invention prior to the October 11, 2002, international filing date of the Wynne et al. reference. Specifically, the Declaration provides a copy of a product description document developed by the inventor prior to September 1, 2001. Accordingly, Wynne et al. is not prior art for the rejection under 35 U.S.C. § 103(a). Applicant further submits that neither Muramatsu et al. not Costanzo et al., either alone or together, form a basis for rejection of claims 1, 5 and 7.

In view of these remarks and the Declaration, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. 103(a) based on Wynne et al., in view of Muramatsu et al. and Costanzo et al.

Therefore, in light of the amendments and remarks set forth above, Applicant believes that all the Examiner's rejections have been overcome. Reconsideration and allowance of claims 1, 5 and 7 are respectfully requested. If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned attorney at 206-622-4900 to resolve the matter.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/William T. Christiansen/
William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:jto

Enclosure:
Declaration of Pamela M. Drake

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

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